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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,437	03/26/2004	Gene A. Bornzin	A04P1029	9799

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PACESETTER, INC.
15900 VALLEY VIEW COURT
SYLMAR, CA 91392-9221

EXAMINER	
REIDEL, JESSICA L	

ART UNIT	PAPER NUMBER
3766	

MAIL DATE	DELIVERY MODE
07/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/810,437	BORNZIN ET AL.	
	Examiner	Art Unit	
	JESSICA REIDEL	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Acknowledgment is made of Applicant's Amendment, which was received by the Office on May 9, 2008. Claims 1-27 have been cancelled. Claims 28-35 are pending.

Specification

2. In view of the response filed May 9, 2008, the objections applied against Applicant's disclosure in the prior Office Action of January 10, 2008 have been withdrawn.

Claim Objections

3. In view of the response filed May 9, 2008, the objections applied against the claims in the prior Office Action of January 10, 2008 have been withdrawn.

4. Claims 28 and 32 are objected to because the recitations of, "the baseline point" in the last two lines of each claim are not consistent with prior recitations of "a baseline point in time". The Examiner suggests changing the last two lines of each claim to read, "wherein the baseline point in time within each of the plurality of cardiac cycles is identified by tracking a pre-ejection interval and then selecting a point in time within the pre-ejection interval." Appropriate correction is required.

5. Claim 28 is also objected to because an inadvertent typographical error exists in the third line rendering the language confusing and/or lacking proper antecedent basis. The Examiner suggests changing the third line of Claim 28 to read, "a ventricular end-diastolic volume (EDV) detection unit for detecting values representative of ventricular EDV; and" instead in order to provide proper antecedent basis for the phrase "the values representative of ventricular EDV" recited in line 9 of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. In view of the response filed May 9, 2008, the 35 U.S.C. 112, first paragraph and second paragraph rejections applied against the claims in the prior Office Action of January 10, 2008 have been withdrawn.

Claim Rejections - 35 USC § 101

7. In view of the response filed May 9, 2008, the 35 U.S.C. 101 rejections applied against the claims in the prior Office Action of January 10, 2008 have been withdrawn.

Allowable Subject Matter

8. The indicated allowability of Claims 28-25 is withdrawn in view of the newly applied interpretations of the previously cited references to ***Wang et al. (U.S. 2005/0080460) (herein Wang)*** and ***Judy (U.S. 2005/0203429)***. Rejections based on these interpretations follow.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. ***Claims 28-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang in view of Judy***. As to Claims 28 and 32, Wang expressly discloses a system for evaluating heart failure within a patient using an implantable medical device (IMD) 10 comprising a ventricular tissue fluid content/status detection unit (monitor 260 in conjunction with microprocessor 224) for detecting intra-thoracic impedance values representative of ventricular tissue fluid content/status and a ventricular tissue fluid-based heart failure evaluation unit operative to detect the progression of heart failure within the patient based on changes in ventricular tissue fluid

content/status (either microprocessor 224 of IMD 10 or associated circuitry of an external device) (see, for example, Wang Figs. 1-2, Abstract, pages 1-2, paragraphs 10-13 and page 4, paragraphs 43-47). In particular, the system is coupled to at least two electrodes for implant within a patient's ventricles (see right ventricular lead 16 and coronary sinus lead 16 of Wang Fig. 1). Wang specifies that the ventricular tissue fluid content/status detection unit is adapted to identify a baseline point in time within each of a plurality of "N" cardiac cycles and to detect a signal representative of the impedance between at least two ventricular electrodes of the system at each baseline point in time. Wang also specifies that the microprocessor 224 portion of the ventricular tissue fluid content/status detection unit may determine a baseline ventricular tissue fluid content/status value based on the impedance signal detected at each baseline point in time for diagnosing a clinically-relevant change in fluid status and/or detecting a progression of heart failure within the patient. The baseline point in time within each of the plurality of cardiac cycles is identified by tracking cardiac sensed or paced events defining times or intervals when the heart volume is not rapidly changing (e.g., the early isovolumetric phase of cardiac systole, late systole near the end of ejection, prior to rapid filling during diastole, or at the end of diastole, prior to the start of systole (see, for example, Wang page 5, paragraph 54, page 6, paragraphs 59-64, page 7, paragraphs 71-73, page 8, paragraphs 77-84, pages 9-13, paragraphs 86-131).

12. Wang discloses the claimed invention except that it is not specified that the detection unit and evaluation unit be determine values representative of ventricular EDV from the measured impedance signals, nor is it specified that the units be operative to detect the progression of heart failure within the patient based on changes in the ventricular EDV of the patient trended/tracked over time. The Examiner, however, considers it to be conventional and well known in the art to detect the progression of heart failure within a patient by tracking or trending changes in the ventricular EDV of the patient determined or detected over time. Furthermore, Judy teaches that it is also well known in the art to determine baseline ventricular EDV values based on intra-thoracic impedance signals detected at a baseline point in time of each of a plurality of cardiac cycles. Specifically, Judy discloses a system for determining the left ventricular EDV of a beating heart comprising a ventricular EDV detection unit 12 adapted to identify at least one baseline point in time within each of a plurality of cardiac cycles for detecting values representative of ventricular EDV, to detect a signal representative of the patient's intra-thoracic

impedance at the baseline points in time, and to determine baseline ventricular EDV values based on the impedance signals detected at the baseline points in time. Judy expressly discloses that the baseline points in time within each of the plurality of cardiac cycles are identified by tracking a pre-ejection interval and then selecting at least two points in time within the pre-ejection interval. Specifically, the ventricular EDV is determined in dependence on both a duration of the diastolic filling time determined for each the plurality of cardiac cycles, a value of the impedance signal detected at the end of the pre-ejection interval and a difference of the value of the first time derivative of the impedance signal between the beginning and the end of the pre-ejection period (see, for example, Judy, pages 2-3, paragraphs 22-46 and pages 6-7, paragraphs 78-98). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Wang in view of Judy such that the detection unit and evaluation unit determine values representative of ventricular EDV from the measured impedance signals and are operative to detect the progression of heart failure within the patient based on changes in the ventricular EDV of the patient trended/tracked over time, in addition to being operative to detect the progression of heart failure within the patient based on changes in the tissue fluid content/status of the patient trended/tracked over time.

13. As to Claims 29 and 33, in addition to the arguments previously presented, Wang also discloses that the microprocessor 224 acts as a heart failure therapy controller that is responsive to the detection of a progression of heart failure to adjust one or more operating parameters (see, for example, Wang page 8, paragraph 79).

14. As to Claims 30 and 34, in addition to the arguments previously presented, Wang discloses that the system may further comprise an implantable drug pump in communication with the microprocessor 224 of the IMD 10, the drug pump being responsive to detection of a progression of heart failure by the heart failure evaluation unit of the IMD 10 to administer a drug to the patient (see, for example, Wang page 8, paragraph 79).

15. As to Claims 31 and 35, in addition to the arguments previously presented, Wang discloses that the system may further comprise an implantable heart failure warning device 228 in communication with the microprocessor 224 of the IMD 10, the warning device 228 being responsive to detection of a progression of heart failure by the heart failure evaluation unit of the

IMD 10 to generate a warning (see, for example, Wang page 4, paragraph 47 and page 8, paragraph 79).

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

Goode (U.S. 7,171,258) (herein Goode) discloses an IMD for trending impedance values or physiological cardiac parameters derived from impedance values in order to monitor the progression of heart failure.

17. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JESSICA REIDEL whose telephone number is (571)272-2129. The Examiner can normally be reached on Monday - Friday, 8:00 AM - 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Carl H. Layno can be reached on (571)272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jessica L. Reidel/
Patent Examiner, Art Unit 3766
July 14, 2008

/Kennedy J. Schaetzle/
Primary Examiner, Art Unit 3766
July 21, 2008